October 31, 2005

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-The-Counter Drug Product, Advance Notice of Proposed Rulemaking, 70 Fed. Reg. 52050 (Sept. 1, 2005) [Docket No. 2005N-0345]

Dear Acting Commissioner von Eschenbach:

We write in response to the Advance Notice of Proposed Rulemaking in docket number 2005N-0345 regarding Barr Laboratories' application for over-the-counter (OTC) status for Plan B® emergency contraception (EC). Given the overwhelming recommendation of the FDA's independent expert advisory committees and professional staff that Plan B® is safe and effective for women of all ages and should be made available OTC, we strongly urge you to stop the unnecessary rulemaking process and make the product available without restrictions for women of all ages without further delay.

We submit these comments in our role as longstanding advocates for policies that improve women's access to quality health care. The National Partnership for Women & Families is a non-profit, nonpartisan organization that uses public education and advocacy to promote quality health care, fairness in the workplace, and policies that help women and men meet the dual demands of work and family. The National Partnership dedicates a tremendous amount of its resources toward ensuring quality health care for women. Underlying our health care work is the fundamental tenet that quality health care is a human right, and that access to the full range of reproductive health services is an essential component of quality health care for women regardless of income, age, geography, race or ethnicity.

Preventing unintended pregnancy through full access to safe and effective contraception is critical to improving women's health. According to labeling approved by the FDA, Plan B® reduces by 89 percent the risk of unintended pregnancy resulting from contraceptive failure or unprotected intercourse.

Prescription EC has substantially reduced the number of unintended pregnancies since its approval in 1999, and the positive impact on public health would be even greater if Plan B® were available OTC. Although there is evidence that emergency contraception can

be used up to five days after sexual intercourse, rapid administration of EC is critical to its efficacy and requires that Plan B® be available OTC to ensure women's access to this important method of contraception. Many women, particularly young women and low-income women, do not have a regular health provider they can rely on for access to Plan B®. Even women who do have a regular health provider may not be able to see their doctor on a weekend or may struggle to fill a prescription quickly due to the increasing number of pharmacists who are unwilling to fill prescriptions for EC.

The decision on Plan B® has been delayed far too long. Following the overwhelming recommendation of the FDA's Joint Advisory Committee to make Plan B® OTC, a decision was expected in February 2004, but following a 90-day delay, the FDA issued a non-approvable letter questioning use of Plan B® by young women. Following submission of a revised application by Barr Pharmaceuticals to make Plan B® OTC for women age 16 and older, the FDA again failed to reach a decision, missing its own deadline in January 2005. This year, Secretary Leavitt promised a final decision by September 1, 2005, but the FDA instead issued the advance notice of proposed rulemaking, yet another unwarranted delay in making this safe and effective medication readily available to women.

According to legal analysis submitted under separate cover by us and other organizations concerned with women's health, the FDA has the authority to offer Plan B® as both a prescription and OTC product, and has taken such action with other products. Although there is precedent for the FDA approving a product as OTC for individuals above a certain age and maintaining prescription status for younger populations, the age distinction is not necessary for Plan B®. Medical and scientific evidence, including a January 2005 article in the Journal of the American Medical Association, do not support the FDA's claim that use of Plan B® by young women would result in its misuse, undermine consistent use of other contraceptives, or cause adverse health consequences. At the December 2003 Advisory Committee meeting, members discussed and rejected the possibility of imposing an age restriction. FDA staff concurred, noting the agency's consistent policy of treating post-pubescent adolescents and adult women the same for the purposes of contraceptive use.

Women rely on the FDA to make public health decisions based on the best scientific evidence available, and evidence consistently indicates that Plan B® is safe for women of all ages. The American Medical Association, the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics – together with more than 70 medical and public health groups – all support increasing women's access to emergency contraception by making it available without a prescription. With half of the approximately three million unintended pregnancies in the U.S. resulting from contraceptive failure, Plan B® has the potential to dramatically improve women's reproductive health. The National Partnership urges the FDA to follow the recommendation of your own scientific advisory committees and staff and approve Plan B® OTC for women of all ages without further delay.